K010641

MAR 3 0 2001

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

10. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name: GE CT-PET System

Establishment Name and Registration Number of Submitter

Name: ELGEMS Ltd.
Registration Number: 9613299
Corresponding Official: Dan Laor
ELGEMS Ltd.
P.O. Box 170
Tirat Hacarmel 30200, ISRAEL

Device Classification

Classification Code: 90 KPS
Panel Identification: Radiology
Classification Name: ECT system (per 21CFR 892.1200)
Common Name: Nuclear Medicine Imaging system
Classification Class: Class II Product

Reason for 510(k) Submission

Modification of legally marketed device.

Identification of Legally Marketed Equivalent Devices

ECAT PET/CT	–	K002715
Positrace Dual Mode PET/CT Oncology System	–	K001681

Device Description

The CT-PET System is a combination of the Advance NXi PET Scanner (K003849) and the LightSpeed QX/i CT Scanner (K000300). In addition to providing CT and PET stand-alone capabilities, it uses the CT images to correct for non-uniform attenuation of the PET images and to facilitate localization of the emission activity in the patient anatomy.

Description of Change or Modification

The Advance NXi PET Scanner (K003849) has been modified to accommodate for the CT subsystem, by including means to align both gantries, a common table and additional software for use of CT for purposes of attenuation correction.

510(k) Summary of Safety and Effectiveness, GE CT-PET System, Page 2

Intended Use of Device

The GE CT-PET System is intended for use in head and whole body attenuation corrected Positron Emission Tomography (PET) imaging, facilitating localization of emission activity in the patient anatomy by means of integrated CT and PET images, and stand alone head and whole body multislice X-ray computed tomography diagnostic imaging.

Summary of Studies

Bench and clinical data show that CT-PET attenuation-corrected images are more uniform than PET images without attenuation correction. The images also demonstrate the localization capabilities of the CT-PET.

Conclusion

In the opinion of ELGEMS Ltd., the CT-PET is substantially equivalent in terms of safety and effectiveness to the legally marketed ECAT PET/CT (K002715) and to the legally marketed Positrace (K001681).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2001

GE Medical Systems Inc.
C/O Reiner Krumme
Division Manager Medical Division
TUV Rheinland of North America, Inc.
12 Commerce Road
NEWTOWN CT 06470

Re: K010641
GE CT-PET System
Dated: March 21, 2001
Received: March 22, 2001
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INTENDED USE

510(k) Number (if known): K010641

Device Name: GE CT-PET System

Indications for Use

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801-109)

OR Over-The-Counter Use_____

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010641